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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NEGIN, RUSSELL SCOTT

ART UNIT PAPER NUMBER

1631

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,861

Applicant(s)

SLAWIN ET AL.

Examiner

Russell S. Negin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/5/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 34-35 and 39-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Upon consideration of the recent Official Gazette notice of November 22, 2005, entitled, "Interim Guidelines for examination of patent applications for patent subject matter eligibility," (www.uspto.gov/web/offices/com/sol/og/2005/week47/patgupa.htm), it is the decision of the Office to enact a 35 U.S.C. 101 rejection.

In regards to claims 34-35 and 39-40 the instant claims are drawn to a medical algorithm. A medical algorithm is non-statutory unless the claims include a step of physical transformation, or if the claims include a useful, tangible and concrete result. It is important to note, that the claims themselves must include a physical transformation step or a useful, tangible and concrete result in order for the claimed invention to be statutory. It is not sufficient that a physical transformation step or a useful, tangible, and concrete result be asserted in the specification for the claims to be statutory. In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, tangible, and concrete result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to

Art Unit: 1631

be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 34-35 and 39-40 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or by including a physical transformation.

As stated in the Official Gazette notice, "The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a Sec. 101 judicial exception, in that the process claim must set forth a practical application of that Sec. 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had "no substantial practical application."). "[A]n application of a law of nature or mathematical formula to a . . . process may well be deserving of patent protection." Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . ."). In other words, the opposite meaning of "tangible" is "abstract.""

Claim Rejections - 35 USC § 102

The rejection of claims 28, 29, 32, 34, and 35 under 35 U.S.C. 102(b) as being anticipated by Ivanovic et al [Nature Medicine, Volume 1, 1995, pages 282-283] is withdrawn due to arguments made by the applicants on pages 9-10 of the Remarks of 5 September 2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 28-31, 32, 34, 35, and 37-42 are under 35 U.S.C. 103(a) as being unpatentable over Ivanovic et al [Nature Medicine, volume 1, 1995, pages 282-

Art Unit: 1631

283] is withdrawn due to arguments made by the applicant in the Remarks of 5 September 2006

Claims 28-31, 32, 34, 35, and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivanovic et al [Nature Medicine, volume 1, 1995, pages 282-283] in view of Newman et al [Radiology, 1995, volume 195, pages 86-90].

Claims 28-31, 32, 34, 35, and 37-42 state:

Claims 28, 29, 34 and 35 are apparatuses and methods for determining the prognoses of prostate cancer patients comprising: a data input means, for input of test information comprising the level or amount of at least one protein in a physiological fluid sample obtained from a human, wherein the at least one protein is selected from the group consisting of various species of protein including transforming growth factors; and a processor, executing the software for analysis of the level or amount of the at least one protein in the sample; wherein the software analyzes the level or amount of the at least one protein in a physiological sample from a human prostate cancer patient treated for clinically localized prostate cancer and provides the risk of prostate cancer progression in the patient.

Claim 32 examines prostate specific antigen as well.

Claims 37-42 dictate when the test is completed (i.e. before or after therapy for prostate cancer).

The article of Ivanovic et al, entitled, "Elevated plasma levels of TGF-beta1 in patients with invasive prostate cancer," states in the first paragraph, "The identification

Art Unit: 1631

of molecular markers for the malignant progression of prostatic adenocarcinoma (CaP) is urgently needed for a more accurate staging and prognosis of the disease."

In Ivanovic et al, the second paragraph states, "TGF-beta1 and prostate specific antigen (PSA) were analyzed from the same plasma samples and the data presented vertically coincident for each patient (see figure on page 283). Plasma from BPH patients [benign prostatic hyperplasia] contained 2.47 ± 0.64 ng ml⁻¹ TGF-beta1 (see table on page 282), a value similar to the 3.99 ± 0.77 ng ml⁻¹ observed for non-BPH males, and published normal values. These results indicate that unlike PSA, plasma TGF-beta1 is not elevated in BPH patients."

The third paragraph continues, "Twelve 'primary' CaP patients (patients for whom TGF-beta1 values were obtained while all or most of their prostate was intact) were incorporated into the study, six with pathological stage II (with tumour confined to the prostate), and six with pathological stage III/IV disease (with tumour having extensive extracapsular extension, seminal vesicle invasion, lymph node metastases or distant metastases)."

Ivanovic et al does not show the necessary software to analyze prostate cancer.

The article of Newman et al, entitled, "Prostate Cancer: diagnosis with color doppler sonography with histologic correlation of each biopsy site," uses computers and software to analyze the presence of prostate cancer in samples taken from men in the study. The "Materials and Methods" section on pages 86-87 explain the relevant procedures and the use of the "ATL-HDI" unit by which the samples were analyzed.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the study of Ivanovic et al both before and after therapy of the prostate cancer, because the therapy does not affect the integrity, or procedure of the test itself; the chronology of the test is irrelevant in determining the prognosis of the disease. It would have been further obvious for someone of ordinary skill in the art at the time of the instant invention to practice the prostate level prognosis of Ivanovic et al in view of the computer software analysis methods of Newman et al because while both methods rely on analogous parameters to analyze the progression of prostate cancer, and while Newman has the proper computer framework for the analysis, Ivanovic et al is a direct application of Newman et al for the problem of TGF-beta1 and prostate cancer prognosis.

Claims 28, 29, 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivanovic et al in view of Newman et al as applied to claims 28-31, 32, 34, 35, and 37-42 above, and further in view of Kattan [Journal of the National Cancer Institute, volume 90, 1998, pages 766-771].

Claim 33 claims the use of a Gleason score for analysis of the prognosis.

Claim 36 claims a nomogram for determining the risk of progression of prostate cancer after local therapy for prostate cancer or the risk of non-prostate confined cancer in a human prostate cancer patient comprising: at least one correlation, wherein the at least one correlation includes the correlation of the level or amount of at least one protein in a sample obtained from a human prostate cancer patient and the risk of progression of the risk of non-prostate confined cancer in the patient, wherein the

Art Unit: 1631

protein is selected from a group including TGF-beta1 and wherein the sample is obtained before or after therapy for clinically localized prostate cancer.

Ivanovic as applied to claims 28-31, 32, 34, 35, and 37-42 above does not show use of a Gleason score or a nomogram for data analysis.

Kattan et al. entitled, "A preoperative nomogram for disease recurrence following radical prostatectomy for prostate cancer." Column 2 on page 766 also shows use of a Gleason grade in analyzing prostate specific antigen (lines 29-30). Figure 2 on page 768 illustrates such a nomogram invoking Gleason scores.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify Newman et al in view of Ivanovic et al as applied to claims 28-31, 32, 34, 35, and 37-42 above, and further in view of Kattan to result in the instantly claimed invention because Kattan adds the ability to plot nomograms for better analysis of the prognosis and assessment of prostate cancer.

Response to Arguments

Applicant's arguments with respect to claims 28-42 have been considered and are persuasive. New grounds of rejection have been applied.

Conclusion

No claim is allowed

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

Art Unit: 1631

(November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).
The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Andrew Wang, Supervisory Patent Examiner, can be reached at (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Yolanda Chadwick, whose telephone number is (571) 272-0514.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSN

6 November 2006



6 November 2006

John S. Brusca 8 November 2006

JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER